

CDER FAST TRACK DESIGNATION REQUESTS RECEIVED*

FISCAL YEAR 1998 - FISCAL YEAR 2015

Fiscal Year (Oct 1 - Sep 30)	Total Requests Received	Granted	Denied	Other**
2015	168	128	35	5
2014	117	89	22	6
2013	97	77	18	2
2012	83	55	24	4
2011	89	54	30	5
2010	102	65	31	6
2009	82	48	28	6
2008	79	48	25	6
2007	91	60	27	4
2006	88	71	16	1
2005	87	64	23	--
2004	81	58	23	--
2003	64	52	12	--
2002	44	33	11	--
2001	53	33	20	--
2000	38	24	14	--
1999	56	36	20	--
1998	27	21	6	--

*Title VIII of FDASIA (implemented July 9, 2012), Generating Antibiotic Incentives Now (GAIN), provides incentives for the development of antibacterial and antifungal drugs for human use intended to treat serious and life threatening infections. Under GAIN, a drug or biologic may be designated as a qualified infectious disease product (QIDP) if it meets the criteria outlined in the statute. A drug or biologic that receives QIDP designation is eligible under the statute for fast track designation (upon request) and/or priority review. This report includes traditional Fast Track Designation Requests, as well as requests received after July 9, 2012, that are associated with GAIN products.

** "Other" accounts for scenarios where the Fast Track Designation Request could not be granted or denied (e.g., the request was withdrawn or the IND was withdrawn or inactivated) or the requests are pending. Pending requests in the previous reporting period may be updated the following year.